MAY 1 1 2001

K004018
510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):

Top Quality Manufacturing
6808 Greenway Ave.
P.O. Box 16864
Philadelphia, PA 19142

Phone: 1-800-468-4886

Contact Person: Marc Sinkow

Date of Summary: February 6, 2001

Trade Name: SkinGard Polycoat Powdered Latex Examination Glove with Protein Content Labeling Claim (200 micrograms or less)

Classification Name: Glove, Patient Examination, Poly

Predicate Device: Tillotson – Pure Advantage Powder Free Nitrile Hypoallergenic Glove K954574

Maxxim Medical Poly Powder Free Medical/Dental Exam Gloves K991615

Intended Use: The Top Quality Skingard Polycoat Glove is intended for medical purposes to be worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Device Comparison:

	SkinGard Polycoat Glove	**Maxxim Poly Powder Free**	**Tillotson Pure Advantage**
510(k), Date		K991615, 7/29/99	K954574, 12/21/95
Testing Completed			
	ASTM D5712-95	ASTM D 6124-97	ASTM
	ASTM D3578-99	ASTM D 3578-95	ASTM
	ASTM D6124		
Intended Use	Examination	Same	Same
Glove	Latex	Same	Non Latex
Packaging	100	100	10,50,100
Glove Coating	Poly	Poly	Nitrile
Powder Free	Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2001

Top Quality Manufacturing, Incorporated
C/O Mr. Arthur Ward
Medical Device Consultant
Regulatory & Marketing Services, Incorporated
962 Allegro Lane
Apollo Beach, Florida 33572

Re: K004018
Trade/Device Name: Skingrad Polycoat Latex Examination Gloves with Protein Labeling Claim (200 Micrograms or Less)
Regulation Number: 880.6250
Regulatory Class: I
Product Code: LYY
Dated: March 19, 2001
Received: March 20, 2001

Dear Mr. Ward:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K004018

Device Name: **Skingard PolyCoat Powdered Latex Examination Gloves With Protein Content Labeling Claim (200 micrograms or less)**

Indications For Use:

The Top Quality Skingard Polycoat Powdered Latex Examination Glove is intended for medical purposes to be worn on the examiner's hand or finger to prevent contamination between patient and examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use__X__
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K004018